USEPA's Registration of Biocides

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Agenda Topics

- Statutory Authority
- OPP and AD background
- Data requirements and Use Patterns
- Test Guidelines
- Human health & ecological risk assessments
- Product testing: efficacy, product chemistry and inert ingredients, and acute toxicity
- Evaluation of substantially similar products
- Product labeling

Statutory and Regulatory Background

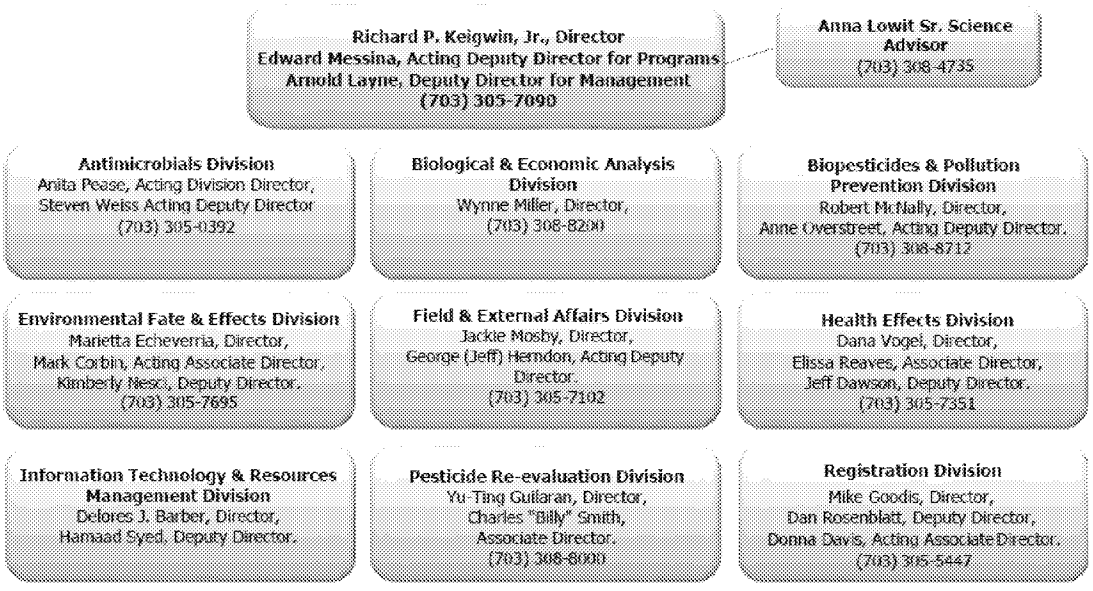
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

- Requires registration of a pesticide product with EPA
- Registration is a license
- Product must meet EPA standards
- Risk-benefit balancing statute

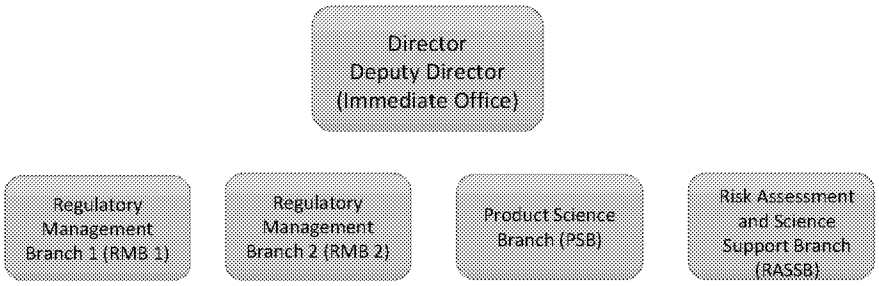
Federal Food Drug and Cosmetic Act (FFDCA)

- Allows EPA to set limits on the nature and level of pesticide residues on food
- Health-based safety standard

Office of Pesticide Programs Organizational Chart



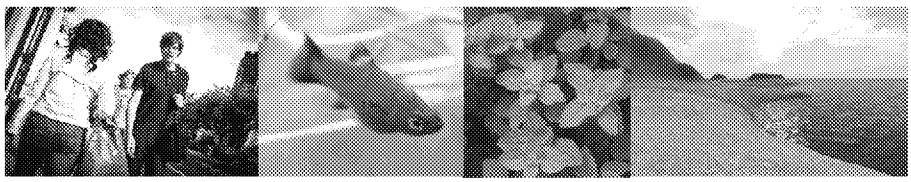
AD's Organizational Structure



Data Requirements and Use Patterns

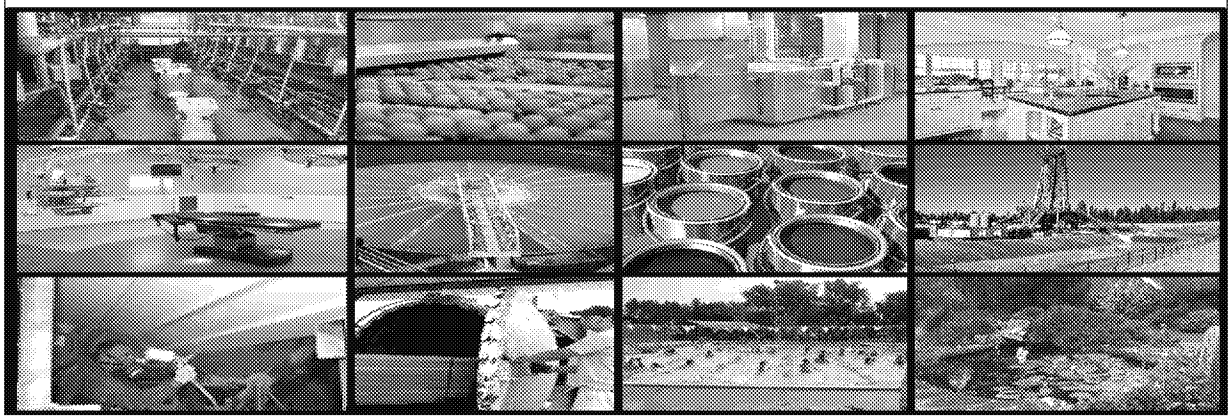
Data Requirements for Pesticides

- EPA assesses a wide variety of potential human health and environmental effects associated with use of pesticide products.
- Registrants must generate data to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide.
- The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain non-target organisms and endangered species that include:
  - humans
  - wildlife
  - plants



158W - 12 Use Patterns

1. Agricultural Premises & Equipment
2. Food Handling/Storage Establishments, Premises and Equipment
3. Commercial, Institutional and Industrial Premises and Equipment
4. Residential and Public Access Premises
5. Medical Premises and Equipment
6. Human Drinking Water Systems
7. Materials Preservatives
8. Industrial Processes and Water Systems
9. Antifouling Coatings and Ballast Water Treatments
10. Wood Preservatives
11. Swimming Pools and Spas
12. Aquatic Areas



Specific Use Sites of Use Site Index (USI)

- USI serves as a compilation of specific use sites commonly listed on antimicrobial product labels
- Specific use sites identify where an antimicrobial pesticide may be used
- Specific use sites are listed within general use patterns and categorized by direct and indirect food use and non-food uses
- Examples of specific use sites and associated general use patterns:

Specific Use Site	General Use Pattern
Metalworking Fluids	Materials Preservatives
Commercial/Industrial Cooling Water (Once-Through)	Industrial Processes and Water Systems
Fruit and Vegetable Rinses	Food Handling/Storage Establishments, Premises and Equipment
Ornamental Ponds/Aquaria	Aquatic Areas
Boat/Ship Hull/Bottom	Antifouling Coatings and Ballast Water Treatments

Scientific Disciplines in 158W

- Product Chemistry, **§158.2210**
- Product Performance, **§158.2220**
- Toxicology, **§158.2230**
- Nontarget Animal Organisms, **§158.2240**
- Nontarget Plant Protection, **§158.2250**
- Applicator Exposure, **§158.2260**
- Post-application Exposure, **§158.2270**
- Environmental Fate, **§158.2280**
- Residue Chemistry, **§158.2290**

Basic Structure of Data Requirements in Part 158W

- 158W Finalized in 2013
- Retains most of the existing "original" pesticide data requirements from Part 158, while tailoring to be specific to antimicrobials
- Studies are tiered and categorized as required (R), conditionally required (CR), or not required (NR)
- Clarifying test notes provide conditions for certain requirements
- Data tables organized by scientific discipline

Test Guidelines

Key Elements of Data Requirements and Test Guideline for Pesticides

- Triggers
  - Exposure & toxicity data are required only if the toxicity criteria and potential for exposure are met
- Alternative testing (not just a check-box approach)
- EPA's test guidelines specify recommended methods to generate data to support the registrations under FIFRA and for setting of a tolerance or tolerance exemption for pesticide residues under section 408 of FFDCA
- Data obtained using test guidelines and submitted to EPA are used to perform risk assessments and make regulatory decisions

Data Requirement Table Structure

Guideline Number Column: These are not data requirements.

Data Requirement Column

Use Pattern Columns

Test Substance by Product Type

Test Note Number

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
850.4225	Seedling emergence, Tier II—dose response.	CR	CR	CR	CR	CR	TEP	TEP	1, 2
850.4250	Vegetative vigor, Tier II—dose response.	CR	NR	CR	CR	CR	TEP	TEP	1, 3
850.4400	Aquatic plant growth (aquatic vascular plant) Tier II—dose response.	R	R	R	R	CR	TGAI, TEP	TGAI, TEP	4, 10
850.5400	Aquatic plant growth (algae) Tier II (dose response).	R	R	R	R	R	TGAI, TEP	TGAI, TEP	4, 5, 6
850.4300	Terrestrial field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9
850.4450	Aquatic field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9

OCSPP Harmonized Test Guidelines - Master List

Last Updated February 2018

The OCSPP harmonized guidelines are organized in the following series:

Series No.	Series Name	Docket ID No.	Last Changed
810	Product Performance Test Guidelines	EPA-HQ-OPPT-2009-0150	February 2018
830	Product Properties Test Guidelines	EPA-HQ-OPPT-2009-0151	November 2008
835	Fate, Transport and Transformation Test Guidelines	EPA-HQ-OPPT-2009-0152	November 2008
840	Spray Drift Test Guidelines	EPA-HQ-OPPT-2009-0153	March 1998
850	Ecological Effects Test Guidelines	EPA-HQ-OPPT-2009-0154	December 2016
860	Residue Chemistry Test Guidelines	EPA-HQ-OPPT-2009-0155	November 2008
870	Health Effects Test Guidelines	EPA-HQ-OPPT-2009-0156	March 2003
875	Occupational and Residential Exposure Test Guidelines	EPA-HQ-OPPT-2009-0157	February 1996
880	Biochemicals Test Guidelines	EPA-HQ-OPPT-2009-0158	February 1996
885	Microbial Pesticide Test Guidelines	EPA-HQ-OPPT-2009-0159	April 2012
890	Endocrine Disruptor Screening Program Test Guidelines	EPA-HQ-OPPT-2009-0576	August 2015

FINAL Guidelines

Final guidelines can be accessed through https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances, and/or via https://www.regulations.gov/ searching on the Docket ID Number provided in the table.

Human Health Exposure and Risk Assessments

Risk in its Simplest Terms

- Risk = Hazard x Exposure
  - Mitigation of risk is often intended to minimize potential exposures
- Risk assessment and risk management are closely related but different processes
  - Risk assessment asks - How risky is the situation?
  - Risk management then asks – What shall we do about it?

Human Health (HH) Sections of 158W

- Toxicology (§ 158.2230)
  - Criteria for testing (potential for exposure must exist)
- Applicator (§ 158.2260)
  - Studies to measure dermal and inhalation exposure
- Post-application (§ 158.2270)
  - Studies to measure dermal, inhalation, and incidental oral exposures
- Residue Chemistry (§ 158.2290)
  - Direct and indirect food uses require residue data

Toxicology Data Requirements: 158.2230

Guideline Number	Data Requirement	Food Uses			Nonfood Uses	
		Direct Food Uses	Indirect Food Uses (> 200 ppb)	Indirect Food Uses (≤ 200 ppb)	Swimming Pools, Aquatic Areas, Wood Preservatives, Metal Working Fluids	All Other Nonfood Uses
Acute Testing						
870.1100	Acute oral toxicity – rat	R	R	R	R	R
870.1200	Acute dermal toxicity	R	R	R	R	R
870.1300	Acute inhalation toxicity - rat	R	R	R	R	R
870.2400	Primary eye irritation - rabbit	R	R	R	R	R
870.2500	Primary dermal irritation	R	R	R	R	R
870.2600	Dermal sensitization	R	R	R	R	R
870.6200	Acute neurotoxicity - rat	R	R	CR	R	CR
Subchronic Testing						
870.3100	90-Day oral toxicity - rodent	R	R	R	R	CR
870.3150	90-Day oral toxicity - nonrodent	R	R	CR	R	CR
870.3200	21/28-Day dermal toxicity	CR	CR	CR	CR	CR
870.3250	90-Day dermal toxicity	CR	CR	CR	CR	CR
870.3465	90-Day inhalation - toxicity - rat	CR	CR	CR	CR	CR

Toxicology Data Requirements: 158.2230

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		Direct Food Uses	Indirect Food Uses (> 200 ppb)	Indirect Food Uses (≤ 200 ppb)	Swimming Pools, Aquatic Areas, Wood Preservatives, Metal Working Fluids	All Other Nonfood Uses
Chronic Testing						
870.4100	Chronic oral toxicity - rodent	R	R	CR	R	CR
870.4200	Carcinogenicity – two rodent species – rat and mouse preferred	R	R	CR	R	CR
Developmental Toxicity and Reproduction						
870.3700	Prenatal developmental toxicity - rat and rabbit preferred	R	R	R	R	R
870.3800	Reproduction and fertility effects	R	R	R	R	R
870.6300	Developmental neurotoxicity	CR	CR	CR	CR	CR
Mutagenicity						
870.5100	Reverse mutation assay	R	R	R	R	R
870.5300 870.5375	*In vitro* mammalian gene mutation	R	R	R	R	R
870.5385 870.5395	*In vivo* cytogenetics	R	R	R	R	R
Special Testing						
870.7485	Metabolism and pharmacokinetics	R	R	CR	R	CR
870.7200	Companion animal safety	CR	CR	CR	CR	CR
870.7600	Dermal penetration	CR	CR	CR	CR	CR
870.7800	Immunotoxicity	R	R	R	R	R

Non-Dietary Exposures

- Occupational Exposures
  - Workers exposed while applying and during post-application
  - Dermal and inhalation routes of exposure
  - Risk mitigation possible by personal protective equipment (PPE) & engineering controls
  - Risk/benefit analysis
- Residential Exposures
  - Homeowners/children/infants exposed while applying and during post-application/bystanders
    - Emphasis on children/infant's activities and age group
  - Dermal, inhalation, incidental oral (hand-to-mouth) routes of exposure
  - Risk mitigation with labeling (e.g., limiting uses, reducing application rates, etc.)
  - Food Quality Protection Act (FQPA)
  - Exposures included in aggregate risk assessment

Need for Applicator Exposure Data

- §158.2260 lists criteria for the requirement of handler exposure data, including:
  - (b)(1)(i) Evidence of potentially significant adverse effects in toxicity studies or (ii) scientifically sound epidemiology/incident data with clear cause-effect, and
  - (b)(2)(i) Dermal or, (ii) inhalation exposure may occur during use
- Exposure data are used by EPA to estimate potential risks

Options for Developing Handler Exposure Data

- Chemical-specific Approach
  - Develop data for each active ingredient
  - Develop data for each labeled use (painting, wiping surfaces, spraying, pouring, etc)
  - Resource intensive, repetitive, impractical
- Surrogate Unit Exposure Approach
  - Antimicrobial Exposure Assessment Task Force - - AEATF II (PR Notice 2009-8/17/09)
  - One set of exposure data for each application method; “unit exposure” concept
  - Saves resources

Dietary Exposures: Direct versus Indirect Food Uses

- Determined by the use pattern (how the pesticide is applied)
- Direct food use is when the antimicrobial is applied to food (e.g., fruit and vegetable washes, fogging of poultry areas, egg wash treatments)
- Indirect food use is when the antimicrobial is in or on an article that comes into contact with food (e.g., dishes, utensils, food-processing equipment, and countertops)
- Presence of residues determines whether a tolerance or exemption from the requirement of a tolerance (tolerance exemption) is required based on the definition of pesticide chemical residue per FFDCA section 201(q)

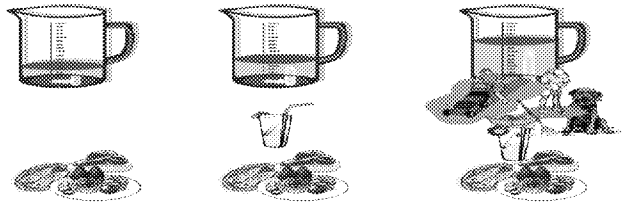
What Type of Dietary Assessment is Required for Indirect Food Uses (most dietary uses are indirect)?

- **Commercial Assessment:** Food-handling establishment, etc.
  - FDA model (1993) = 4000 cm^2 x 1 mg/cm^2 x %AI
  - ACC Food Contact Sanitizing Solutions Model (FCSSM)
  - https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/food-contact-sanitizing-solutions-model-fcssm
- **Residential Assessment:** *Strictly* residential settings (*e.g.*, kitchen counter tops, etc in homes)
  - Adjusted FDA model = 2000 cm^2 x 1 mg/cm^2 x %AI
  - **I**ndirect **D**ietary **R**esidential **E**xposure **A**ssessment **M**odel (IDREAM)
  - https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/indirect-dietary-residential-exposure-assessment

Risk Informs Regulatory Decision
How is it Expressed?
How is it Communicated to Pesticide Users?

Risk = Exposure x Hazard

- Non-Dietary (Applicator) risk is expressed as a MOE (Margin of Exposure)
- Dietary Risk is expressed as %PAD (Population Adjusted Dose)
- An aggregate risk assessment is required if there are food uses
  - Aggregate = Food + drinking water + residential uses



Ecological Risk Assessments

Ecological Data Requirement Sections

- In Subpart 158 W the environmental fate and ecological effects data requirements are located in three sections
- § 158.2240: Nontarget organism
- § 158.2250: Nontarget plant protection
- § 158.2280: Environmental fate

Ecological Risk Assessment

- Evaluates the likelihood that adverse ecological effects may occur as the result of exposure to a pesticide
- Considers:
  - Use Pattern
  - Environment: Terrestrial and/or Aquatic
  - Ecotoxicity Endpoints
  - Exposure:
    - Acute and/or Chronic
    - Freshwater and/or Saltwater (Estuarine/marine)
    - Water column and/or Sediment

Ecological Effects Toxicity Data

- Acute toxicity endpoint for nontarget animals is the LD_{50} or LC_{50} (dose or concentration that kills 50% of animals tested)

- Chronic toxicity endpoints for nontarget animals are the lowest dose or concentration where no adverse effects such as reproduction or non-lethal impairment are observed (NOAEL *No Observed Adverse Effect Level* or NOAEC *No Observed Adverse Effect Concentration*)

- Plant effects endpoints are lowest dose or concentration that growth is impaired. Neither acute nor chronic.

Aquatic Toxicity Endpoints

- Fish and Aquatic Invertebrates – water column
  - Acute Toxicity: LC50 (mortality) or EC50 (immobility)
  - Chronic Toxicity: NOAEC (reproduction, growth)
- Aquatic Invertebrates – sediment
  - Acute: EC50
  - Chronic: NOAEC
- Aquatic Plants
  - Listed species: EC05 (or NOAEC)
  - Non-listed species: EC50

Terrestrial Toxicity Endpoints

- Mammals
  - Rat/Mouse data submitted for Human Health
- Birds
  - Acute oral: LD50
  - Dietary: LC50
  - Chronic: NOAEC
- Bees
  - Acute oral: LD50

Antimicrobial Pesticides – Exposure Estimates

- **Deterministic (point estimate)** assessment - Risk Quotient (RQ) calculations
  - End-of-pipe concentrations for lakes and estuaries and sediment organisms
  - Direct applications to water body or leaching from a boat, dock, pier or treated surface. Uses the standard Farm Pond or Drinking Water Index Reservoir from PRZM-EXAMS model
  - MAMPEC (Marine Antifoulant Model to Predict Environmental Concentrations)
- Models: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

Antimicrobial Pesticides – Exposure Estimates

- **Probablistic** assessment - Evaluate exposure to aquatic organisms from pesticides which are rinsed **Down the Drain**
  - Environmental Fate Screening Tool (E-FAST)
    - Two modules from EFAST. **Municipal** (community based) and **Industrial** (manufacturing treatment facility)
    - Based on distribution of size of facility and size of receiving stream. Appropriate for flowing water. Not appropriate for lakes or estuaries
  - Uses toxicity endpoints and output expressed as # of days of exceedance of Concentrations of Concern (COCs) for aquatic organisms

Antimicrobial Pesticides – Risk Characterization

Critical element for both human health and ecological risk assessment

- Products are designed to control microorganisms and fouling organisms and are expected to cause harm to sludge, algae, and aquatic invertebrates if they are exposed
- Assumptions made during assessment because of toxicity and exposure uncertainties may have major impacts on the predicted risk
- Monitoring data and incident reports help characterize the risk, but in many circumstances may not be available or complete
- Models are extremely useful, but limited

Product Efficacy Testing

Two types of microorganisms:

Public Health Microorganisms:

- Kills pathogenic organisms
- Treats potable water or pools/spas
- Kills animal viruses
- Controls public health biofilm

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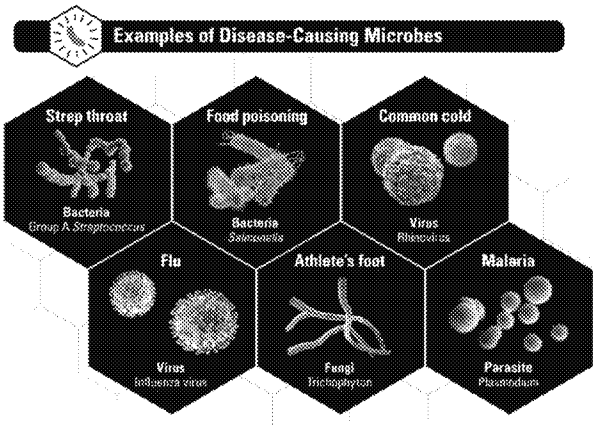
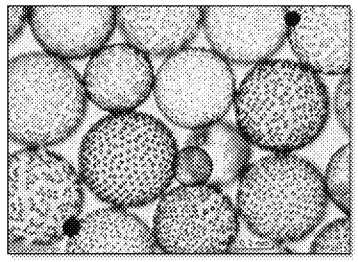
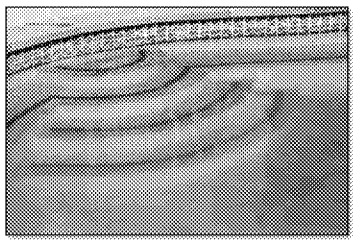
Registrant must submit efficacy data to substantiate claims



Two types of microorganisms:





Non-Public Health:

- Presence of microorganism does not normally lead to infection or disease in humans (e.g. slime and odor causing bacteria, spoilage bacteria, fouling bacteria, algae)

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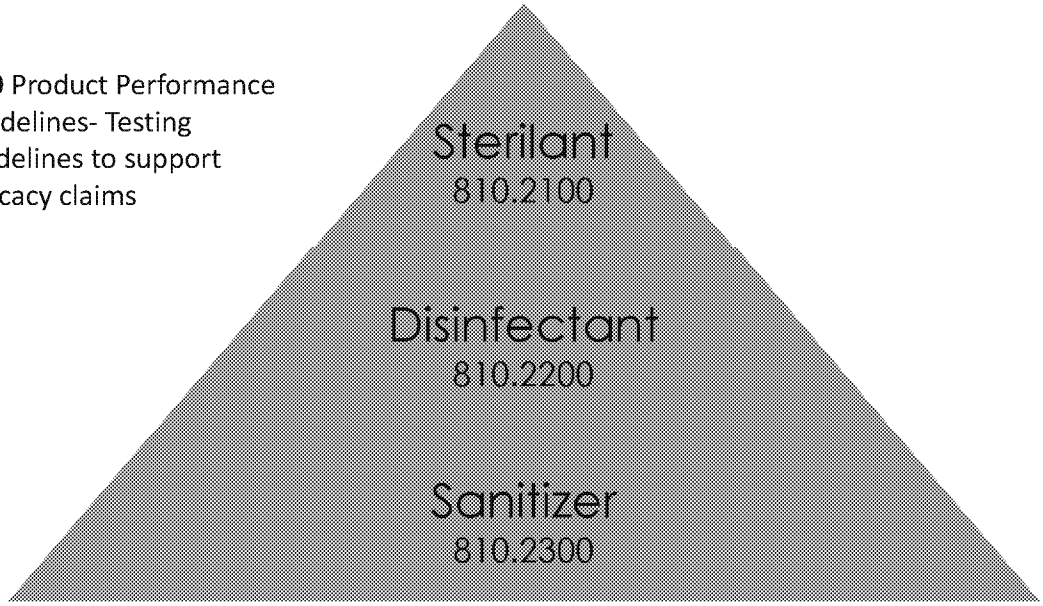
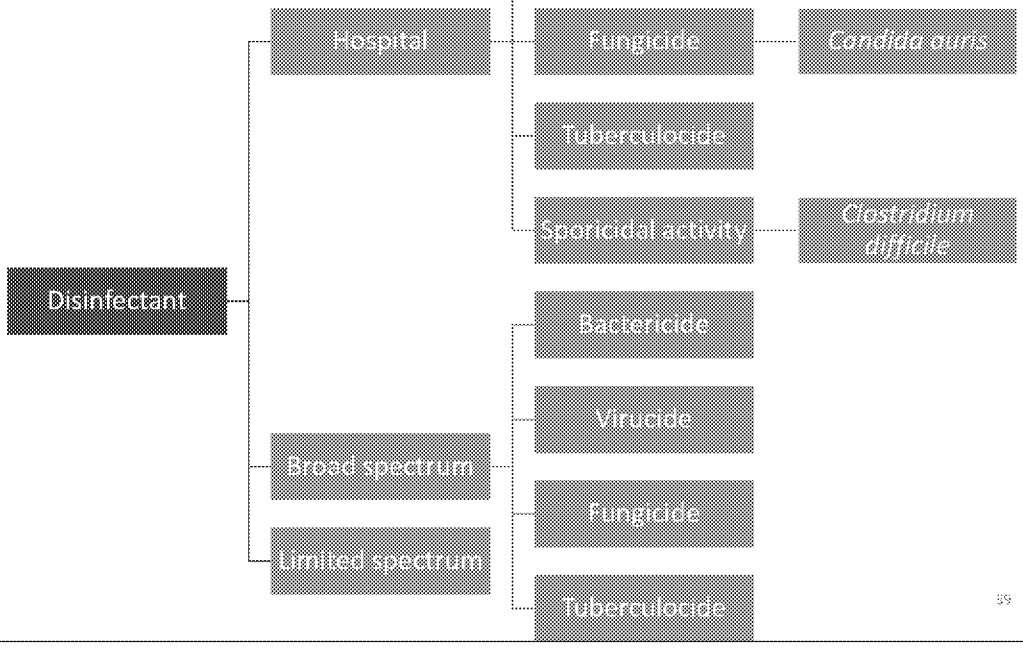
- Registrant does not need to submit efficacy data to substantiate claims
- Company needs to always have data on file and submit them to EPA upon request

Levels of Efficacy

810 Product Performance Guidelines- Testing guidelines to support efficacy claims



Hard Surface Disinfectant Claims



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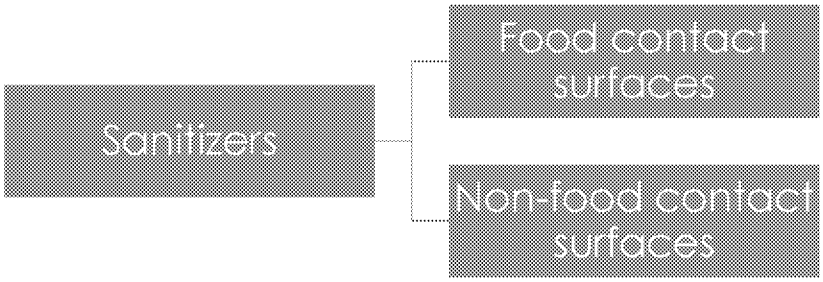
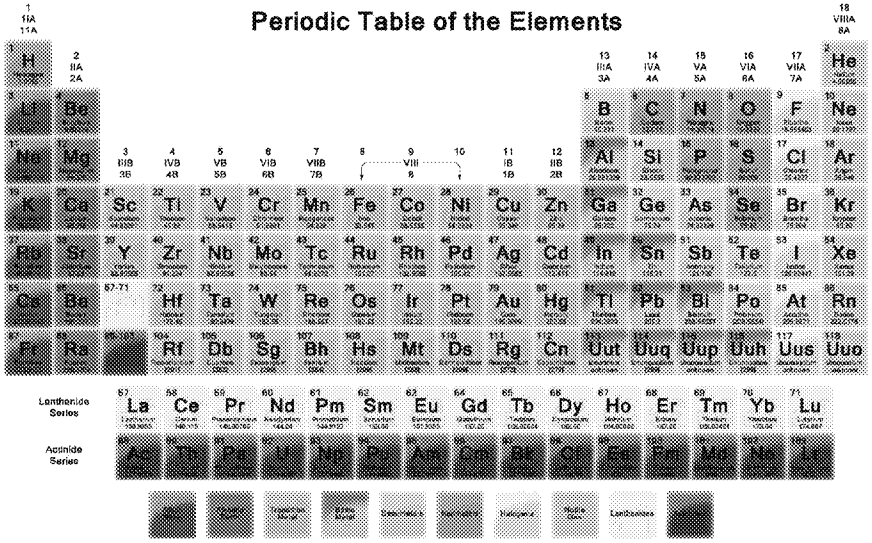
Hard Surface Sanitizer Claims



Product Chemistry and Inert Ingredients

Product Chemistry



Product Chemistry

- Data are required for all pesticide products and are not use-specific
- Product chemistry data fall into two major categories:
  - information on product identity, composition, and analysis (Group A)
  - information on specific physical and chemical characteristics of pesticide chemicals and products (Group B)
- The Guidelines for Product Chemistry are the Series 830 - Product Properties Test Guidelines
- These data support the conclusions expressed in the Confidential Statement of Formula (CSF). Certain information submitted for this section will be treated as confidential business information (CBI)

Series 830 - Product Properties Test Guidelines

The final Product Properties Test Guidelines are generally intended to meet testing requirements for physical and chemical properties of pesticide products under FIFRA and toxic substances under TSCA.

Group A — Product Identity, Composition, and Analysis

830.1000 - Background for Product Properties Test Guidelines (March 1998)
830.1550 - Product Identity and Composition (August 1996)
830.1600 - Description of Materials Used to Produce the Product (August 1996)
830.1620 - Description of Production Process (August 1996)
830.1650 - Description of Formulation Process (August 1996)
830.1670 - Discussion of Formation of Impurities (August 1996)
830.1700 - Preliminary Analysis (August 1996)
830.1750 - Certified Limits (August 1996)
830.1800 - Enforcement Analytical Method (August 1996)
830.1900 - Submittal of Samples (November 2008)

Group B — Physical/Chemical Properties

830.6302 - Color (August 1996)
830.6303 - Physical State (August 1996)
830.6304 - Odor (August 1996)
830.6313 - Stability to Normal and Elevated Temperatures, Metals, and Metal Ions (August 1996)
830.6314 - Oxidation/Reduction Chemical Incompatibility (August 1996)
830.6315 - Flammability (August 1996)
830.6316 - Explodability (August 1996)
830.6317 - Storage Stability (June 2002)
830.6319 - Miscibility (August 1996)
830.6320 - Corrosion Characteristics (August 1996)
830.6321 - Dielectric Breakdown Voltage (August 1996)
830.7000 - pH (August 1996)
830.7050 - UV/Visible Absorption (August 1996)
830.7100 - Viscosity (August 1996)
830.7200 - Melting Point/Melting Range (March 1998)
830.7220 - Boiling Point/Boiling Range (August 1996)
830.7300 - Density/Relative Density/Bulk Density (June 2002)
830.7370 - Dissociation Constants in Water (August 1996)
830.7520 - Particle Size, Fiber Length, and Diameter Distribution (August 1996)
830.7550 - Partition Coefficient (n-octanol/water), Shake Flask Method (August 1996)
830.7560 - Partition Coefficient (n-octanol/water), Generator Column Method (August 1996)
830.7570 - Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography (August 1996)
830.7840 - Water Solubility: Column Elution Method; Shake Flask Method (March 1998)
830.7860 - Water Solubility, Generator Column Method (March 1998)
830.7950 - Vapor Pressure (August 1996)

Group B-Physical/Chemical Properties Self-Certification

Pesticide Registration (PR) Notice 98-1

- Self-Certification of Product Chemistry Data
  - Registrants submits one-page summary of Group B data.
  - *No longer required to submit study upon which the summary is based*

Self-Certification:

- Voluntary
- Intended to simplify and accelerate registration and reregistration

Products Eligible for Self-Certification:

- MUP and EP produced by a non-integrated formulation system (product with a registered source of active ingredient)

Benefits:

- Simplifies and accelerates processing of applications
- Reduction of paperwork
- Saves time, effort, and resources
- ~30% of new registrations AD has received, used Self-Certification

https://www.epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments

Inert Ingredient - Operational Definition

- Inert ingredients are intentionally-added components in pesticide product formulations, that do not act as an active ingredient *against the targeted pest*
- Inert ingredients have various functions in pesticides (e.g., solvents, carriers, emulsifiers, thickeners, pH control agents) and does not include impurities, degradates, or metabolites
- All inert ingredients must be cleared by the Agency. EPA regulates the entire product formulation; not just the active ingredient. The FIFRA standard for inerts is the same as with actives. FFDCA requires the establishment of a tolerance or exemption for inerts in food use formulations.
- The review process of new inert ingredients is similar to active ingredients.

Product Acute Toxicity

Product-specific Acute toxicity studies

- Acute oral, dermal, and inhalation toxicity, eye and skin irritation, and skin sensitization – the so-called "6-pack"
- Required in the Regulations → 40 CFR 158.2230 (Toxicology)
- Defined in OCSPP 870-series Guidelines (870.1100 - 870.2600) → Test Guidelines
- Each study is evaluated individually and is assigned its own acute Toxicity Category for product labeling

Acute toxicity 6-pack

Guideline	Study
870.1100	Acute Oral Toxicity
870.1200	Acute Dermal Toxicity
870.1300	Acute Inhalation Toxicity
870.2400	Eye Irritation
870.2500	Skin Irritation
870.2600	Dermal Sensitization

Labeling

- Endpoint: Labeling – Human hazard and First Aid statements
- Statements are defined by guidance in *Label Review Manual* and are determined by acute Toxicity Categories, which are determined by studies
- Toxicity Categories: →
  - Toxicity category I is highly toxic or severely irritating
  - Toxicity category II is moderately toxic or moderately irritating
  - Toxicity category III is slightly toxic or slightly irritating
  - Toxicity category IV is practically non-toxic or not an irritant

Alternative Testing for Acute Toxicity

- Current guidance documents and policy:
  - Updated Guidance for Testing Antimicrobial Cleaning Products (ADCPs) for Their Potential to Cause Eye Irritation https://www.epa.gov/pesticide-registration/non-animal-testing-approach-epa-labeling-eye-irritation
    - Bovine Corneal Opacity and Permeability assay (BCOP)
    - EpiOcular assay (EO)
    - Cytosensor Microphysiometer (CM) assay
  - Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis https://www.epa.gov/sites/production/files/2016-11/documents/acute-dermal-toxicity-pesticide-formulations_0.pdf
  - Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing https://www.epa.gov/pesticides/epa-releases-draft-policy-reduce-animal-testing-skin-sensitization

Evaluation of Substantially Similar Products

Identical/Substantially Similar ("Me-Too") Product

An "identical/substantially similar" pesticide registration application refers to products that are:

- Identical/substantially similar in its uses and formulation to one or more products that are currently registered and marketed in the U.S.; or
- Differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.
- Can include identical repack registrations or be old (existing) chemical, new product registrations.

"Identical/Substantially Similar" Products

Examples of when a proposed product is not considered "identical/substantially similar" include:

- The maximum use rate of the product is increased beyond that which is currently registered;
- Any changes that might affect the pesticide residues in food or feed commodities or exposure to non-target organisms; or
- A reentry interval (REI) for a treated area is lowered.

CATSAC, formerly known as the Similarity Clinic

- Similarity Clinic was formalized in 1991 to ensure consistency in review of the acute toxicity "6-pack" data.
- Similarity Clinic reorganized in late 2016 and was re-named the CATSAC:

  Chemistry and Acute Toxicology Science Advisory Council
- Formal membership now includes:
  - chemists/toxicologists/regulatory scientists
  - Representatives from Divisions across OPP
- CATSAC reviews acute toxicity "6-pack" studies and waiver rationales
- CATSAC considers substantially similar data and data bridging rationales

CATSAC

Active Ingredient (a.i.) considerations for substantially similar toxicity:

- % a.i. proposed product ≤ % a.i. cited product
- Use dilution is similar for proposed and cited product
- Proposed product has no additional active ingredients compared to cited

FY'17 CATSAC Summary

	Acute Oral	Acute Dermal	Acute Inhalation	Eye Irritation	Skin Irritation	Skin Sensitization
All 6 pack waived	1	1	1	1	1	1
Bridged	4	4	3	2	2	2
Waived/Assigned Tox Category	2	2	2	3	3	2
Waiver Rationales			3			
Tox Category Assigned Based on Pub. Lit. (OECD SIDS/IUCLID)	1	1	1	1	1	1
Studies Saved	8	8	10	7	7	6
Test Dollars Saved ($)	40,000	48,000	290,000	21,000	21,000	54,000
Paperwork Burden Cost Saved ($)	11,312	16,560	100,040	5,698	5,698	17,340
Paperwork Burden Hours Saved	160	240	1430	84	84	246

Product Labeling

The Pesticide Label

- **The Label is the law:**

  "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

- **The Label is the primary tool of the Office of Pesticide Programs to minimize pesticide exposures to mitigate risk concerns.**

- **The Label is how the EPA communicates with end users.**

- **Label language is determined based on the various reviews conducted by the Office of Pesticide Programs.**

QUESTIONS?